

## **STATEMENT OF WORK (SOW)**

The Cleveland VA Medical Center (VAMC), Cleveland OH has a requirement for Radiopharmaceutical Isotopes for patient care. The Contractor is to provide Radiopharmaceutical products as listed herein, as requested by authorized VA Staff, in accordance with Public Law 104-262 and 38 USC 8153 in order to support the VAMC, Cleveland OH.

DELIVERIES: Deliveries to Cleveland VAMC shall be made to:

Louis Stokes Cleveland VAMC  
Nuclear Medicine Service  
Room N08  
10701 East Blvd  
Cleveland, OH, 44106

1. Contractor shall provide routine delivery and pick-up of items during the hours of 8:00 a.m. to 4:30 p.m., Monday through Friday, excluding holidays. Orders can be placed via telephone, fax or email by staff nuclear medicine technologists or physicians assigned to the Nuclear Medicine Service at the VAMC and will indicate the required calibration time. Delivery personnel will be required to display a photo ID badge at all times.
2. All routine deliveries of radiopharmaceuticals, ordered by 4:30 p.m. the previous day, shall be at the VA facility by at least 0.5 hours before the requested calibration time the next business day.
3. Emergency and additional request orders may be made and shall be delivered within two (2) hour of placement of the order, 24 hours a day, 7 days a week. Orders placed after 4:30PM weekdays and on weekends shall be considered an emergency.
4. Pre-calibrated doses should not expire within 4 hours of calibration time requested by the Nuclear Medicine Service. Pre-calibrated doses of F-18 and F-18 compounded doses shall not expire within 2 hours of the calibration time.
5. Stat Orders (emergency doses ordered during normal business hours: 8:00 a.m. – 4:30 p.m.) shall be delivered within two (2) hour of placement of the order. Orders placed after 4:30PM weekdays and on weekends shall be considered an emergency.
6. The 10 Federal Holidays observed by the Federal Government are:

New Year's Day	January 1
Martin Luther King's Birthday	3 <sup>rd</sup> Monday in January
Presidents Day	3 <sup>rd</sup> Monday in February
Memorial Day	Last Monday in May
Independence Day	July 4
Labor Day	1 <sup>st</sup> Monday in September
Columbus Day	2 <sup>nd</sup> Monday in October
Veterans Day	November 11
Thanksgiving Day	4 <sup>th</sup> Thursday in November
Christmas Day	December 25 <sup>th</sup>

The President of the United States of America may declare additional days as a Federal holiday, and if so, this holiday will automatically be added to the list above. When a holiday falls on a Sunday, the following Monday shall be observed as a Federal holiday. When a holiday falls on a Saturday, the preceding Friday shall be observed as a Federal Holiday.

7. All products provided under this contract shall meet all requirements of the Nuclear Regulatory Commission (NRC). All products provided under this contract shall be packaged and shipped in accordance with the requirements of the NRC and Department of Transportation (DOT). All products returned will also be packaged in accordance with the requirements of the NRC and DOT. All products provided under this contract shall be from an FDA approved source with an available NDC number from the manufacturer.
8. Compliance with all OSHA manufacturing, packaging and shipping regulations is required. **The awardee shall provide a copy of Type A package certification and certificates of DOT and OSHA training for couriers prior to the commencement the contract.**
9. The contractor shall guarantee the quality of all radiopharmaceuticals. Quality control shall include percent tag and MO99 breakthrough as appropriate. The Contractor shall provide Quality Control on each agent dispensed. The Contractor shall guarantee the quality of all radiopharmaceuticals. Only those products that pass quality control may be sent to the VA. The Contractor shall provide complete documentation on Quality Control results upon request.
10. The contractor shall label all products to indicate the amount of radiopharmaceutical, preparation time, expiration time and date to comply with specific facility requirements.
11. The contractor shall invoice at least once a month to the Nuclear Medicine Service indicating the period covered, billing date, name of preparation, quantity and dollar amount.
12. The contractor shall not add to the invoice the cost of overages. Any cost to replace damaged or incorrect products will be at the cost of the contractor. Replacements shall be received within 48 hours of notification by the VAMC.
13. The Contractor shall provide upon request, documentation of inventory, disposal and patient dose records, which documents compliance with Nuclear Regulatory Commission (NRC).
14. RECALLED AND DEFECTIVE PRODUCTS: the Contractor will immediately notify the Contracting Officer of any recalls of product or other important product safety issues. As appropriate, the Contractor will replace and/or reimburse recalled / defective products at no cost to the Government. The Contractor may be liable for costs of processing recalls, i.e. administrative and clinical services to replace recalled / defective products.
15. It is preferred that where applicable the contractor will provide Low Enriched Uranium (LEU) sourced Tc products vice High Enriched Uranium (HEU) sourced. The contractor should indicate which products and in which years that products will come from LEU sources. It will be expected

that offerors provide LEU sourced Tc products to the VAMC beginning no later than calendar year 2016.

**16. Performance Period will be twelve (12) months from date of award with one (1), four (4) month option period to extend the term of the contract.**

**17. Offers will only be considered from Offerors that are licensed by the Nuclear Regulatory Commission who are regularly established in the business of providing radionuclides as called for in this RFQ. Offerors shall provide copies of licenses and certification in response to this RFQ.**

### **Proposal Evaluation and Award**

This is a competitive Request for Quotations (RFQ) that will be evaluated under FAR Part 12 and Part 13. The Government intends to make one (1) award from this RFQ. The Government will award a contract resulting from this solicitation to the responsible offeror whose offer conforming to the solicitation will be most advantageous to the Government, price and other factors considered. The following factors will be used to evaluate offers:

Price

Past Performance

Technical (capability of offer to meet the Government's needs)

**Offers should be submitted electronically by 1630, 9/3/2014 to [thomas.moore9@va.gov](mailto:thomas.moore9@va.gov). Offers should include the following 3 sections to their offers:**

1. A completed Cost/Price Schedule filled in below or as a separate Excel spreadsheet. For the purpose of evaluation the total price including option periods will be evaluated.
2. Past Performance to include the following information
  - a. Identify at least 3 recent (within the past 3 years) Federal, State, local Government or private contracts that are similar in size and scope to this requirement.
  - b. Dollar Value
  - c. Dates of performance
  - d. Name of Agency/Facility
  - e. Point of Contact along with contact information
  - f. A brief description of the work effort to demonstrate the relationship between the reference contract and the proposed effort
3. Technical description in sufficient detail to allow the Government to ascertain the Offerors capability to meet, in addition to the items listed in the cost/price schedule, the requirements indicated in the SOW and should include at a minimum the following information:
  - a. Ability to meet the required delivery timeframes.
  - b. Ability to meet compliance and regulation requirements.
  - c. Quality control measures.
  - d. Ability to supply LEU sourced products no later than the start of calendar year 2016.

An Offeror's initial proposal should contain the best terms from a price and technical standpoint. Offerors are reminded that representatives from your company **SHALL NOT** contact any Cleveland VAMC personnel to discuss this RFQ during the solicitation and evaluation process. All questions and concerns regarding this solicitation shall be directed to the Contracting Officer. Questions must be in writing, sent to [thomas.moore9@va.gov](mailto:thomas.moore9@va.gov) and received no later than 8/22/2014.

### Cost/Price Schedule

The quantities listed below are yearly estimates only and do not guarantee that the Government will require the total quantities of each item or limit the Government's ability to exceed the quantities. The contractor is to fill in a price each line item and a total price. Any proposed substitute items need to be clearly marked as such and which item the substitution is proposed for.

<b>BASE YEAR</b>			
<b>Item</b>	<b>Est. Qty</b>	<b>Price Per</b>	<b>Total Price</b>
99M TC Sulfur Colloid: 1 to 6 Millicurie	90		
99M Tc-MDP: 25 Millicurie	5		
99M Tc Mebrofenin: 5 to 10 Millicuries	90		
99M TC-MAG-3 unit dose: 2 to 15 Millicurie	60		
99M Tc-Tetrofosmin (generic): 10 to 35 millicurie	5		
99M TC MAA : 1 to 6 Millicurie	60		
IN-111 Pentetreotide: 2 to 7 Millicurie	25		
99M TC04-: 25 Millicurie	120		
99m Tc- Sestamibi (generic): 10 to 35 millicurie	3900		
99m Tc- White Blood Cell labeling per study (25 mCi)	45		
IN-111 White Blood Cell labeling per study (0.5 to 1 millicurie)	2		
99m TC DTPA: 2 to 60 Millicurie	55		
I-123: Iodine Capsule 200 Microcuries	250		
ULTRATAG KIT	20		
99M Tc-Filtered Sulfur Colloid: 0.5 to 1 Millicurie	70		
18F : FDG – Fluorodeoxyglucose 10 Millicurie	2100		
18F : NaF – Sodium Fluoride 10 Millicurie	25		
123I: Ioflupane (DATSCAN) dose	10		
123I: MIBG dose	5		
Cold PYP vials	75		
TOTAL BASE YEAR PRICE			
<b>OPTION PERIOD ONE (1)</b>			
<b>Item</b>	<b>Est Qty</b>	<b>Price Per</b>	<b>Total Price</b>
99M TC Sulfur Colloid: 1 to 6 Millicurie	30		
99M Tc-MDP: 25 Millicurie	2		
99M Tc Mebrofenin: 5 to 10 Millicuries	30		
99M TC-MAG-3 unit dose: 2 to 15 Millicurie	20		
99M Tc-Tetrofosmin (generic): 10 to 35 millicurie	2		
99M TC MAA : 1 to 6 Millicurie	20		

IN-111 Pentetreotide: 2 to 7 Millicurie	8		
99M TC04-: 25 Millicurie	40		
99m Tc- Sestamibi (generic): 10 to 35 millicurie	1300		
99m Tc- White Blood Cell labeling per study (25 mCi)	15		
IN-111 White Blood Cell labeling per study (0.5 to 1 millicurie)	1		
99m TC DTPA: 2 to 60 Millicurie	18		
I-123: Iodine Capsule 200 Microcuries	83		
ULTRATAG KIT	8		
99M Tc-Filtered Sulfur Colloid: 0.5 to 1 Millicurie	23		
18F : FDG – Fluorodeoxyglucose 10-13 Millicurie	700		
18F : NaF – Sodium Fluoride 10-13 Millicurie	8		
123I: Ioflupane (DATSCAN) dose	4		
123I: MIBG dose	2		
Cold PYP vials	25		
TOTAL OPTION PERIOD PRICE			
Total			